K113208

JAN 26 2012

510(k) Summary

Submitter:	Apex Biotechnology Corp. No. 7, Li-Hsin Road V, Hsinchu Science Park Hsinchu, 30078 CHINA (TAIWAN)
Contact Person:	Hsue-mei Lee Manager of Quality Assurance Department Apex Biotechnology Corp. No. 7, Li-Hsin Road V, Hsinchu Science Park Hsinchu, 30078 CHINA (TAIWAN) email: hsue-mei@apexbio.com Phone: 011-886-3-5641952 FAX: 011-886-3-5678302
Date Prepared:	December 27, 2011
Trade Names:	GAL-1A Blood Glucose Monitoring System GAL-1A Blood Glucose Test Strips
Classification:	Glucose test system, 21 CFR 862.1345, Class II
Product Codes:	CGA, NBW
Predicate Device:	GAL-1C Blood Glucose Monitoring System (k102816) GAL-1C Blood Glucose Test Strip (k102816)
Device Description:	The GAL-1A blood glucose meter and GAL-1A test strips are used for testing of blood glucose by self-testers at home. Contrex Plus III Glucose Control Solutions are used for quality control testing of the system.

Intended Use:	GAL-1A Blood Glucose Monitoring System: The GAL-1A Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). Testing is done outside the body (In Vitro diagnostic use). It is indicated for lay use by people with diabetes, as an aid to monitoring levels in Diabetes Mellitus and should only be used by a single patient and it should not be shared. It is not indicated for the diagnosis or screening of diabetes or for neonatal use. GAL-1A Blood Glucose Test Strips: The GAL-1A Blood Glucose Test Strips are to be used with the GAL-1A Blood Glucose Meter to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm. Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). They are not indicated for the diagnosis or screening of diabetes or for neonatal use.

Comparison of Technological Characteristics:	The GAL-1A meter has been modified relative to the predicate by orienting the Liquid Crystal Display (LCD) vertically and rearranging its icons, plus altering the meter case to accommodate the LCD change. The GAL-1A meter uses the same test algorithm as the predicate meter. The GAL-1A test strips are identical to their predicate devices.
Non-Clinical Testing:	Testing was conducted as follows: EMC and Electrical Safety, drop testing, disinfection performance (robustness of meter to multiple cleanings and disinfections), software verification and validation, and linearity testing with validation of Lo/Hi detection. Results demonstrate substantial equivalence to the predicate system.
Clinical Testing	A user study was conducted to evaluate ease-of-use of the system and ease-of-understanding of the User's Manual. Results demonstrate substantial equivalence to the predicate system.
Conclusion:	Clinical and non-clinical testing demonstrated that the GAL-1A system performs in a substantially equivalent manner to that of the predicate. We conclude that the GAL-1A meter and GAL-1A test strips are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Apex Biotechnology Corp.
c/o Hsue-mei Lee
No. 7, Li-Hsin Road V, Hsinchu Science Park
Hsinchu, 30078
CHINA (TAIWAN)

JAN 2 6 2012

Re: k113208
Trade Name: GAL-1A Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: NBW, CGA
Dated: December 27, 2011
Received: December 28, 2011

Dear Hsue-mei Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K113208

Device Name: GAL-1A Blood Glucose Monitoring System

Indications for Use:

GAL-1A Blood Glucose Monitoring System:

The GAL-1A Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). Testing is done outside the body (In Vitro diagnostic use). It is indicated for lay use by people with diabetes, as an aid to monitoring levels in Diabetes Mellitus and should only be used by a single patient and it should not be shared. It is not indicated for the diagnosis or screening of diabetes or for neonatal use.

GAL-1A Blood Glucose Test Strips:

The GAL-1A Blood Glucose Test Strips are to be used with the GAL-1A Blood Glucose Meter to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm. Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). They are not indicated for the diagnosis or screening of diabetes or for neonatal use.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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